IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9194

Bartle, J. January 10, 2014

The Estate of Thomas Harold ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether the Estate met

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Esther A. Harold, Thomas Harold's ("Mr. Harold") spouse, also has submitted a derivative claim for benefits.

its burden of proving that the claim was not based, in whole or in part, on any intentional material misrepresentation of fact.[3]

To seek Matrix Benefits, a representative claimant[4] must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In June, 2002, Mr. Harold submitted a completed Green Form to the Trust signed by his attesting physician,

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3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs, or beneficiaries. See Settlement Agreement § II.B.

Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed at least 355 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated August 12, 1998, Dr. Evans attested in Part II of the Green Form that Mr. Harold suffered from severe mitral regurgitation, an abnormal left ventricular end-systolic dimension, an abnormal left atrial dimension, and a reduced ejection fraction of less than 30%.[5] Based on such findings, Mr. Harold would be entitled to Matrix A-1, Level II benefits in the amount of $424,211.[6]

In the report of Mr. Harold's August 12, 1998 echocardiogram, the reviewing cardiologist, Robert E. Roeder, M.D., F.A.C.C., observed that Mr. Harold had "moderate to severe mitral valve insufficiency." Dr. Roeder, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present

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5. Dr. Evans also attested that Mr. Harold suffered from New York Heart Association Functional Class III symptoms. This condition is not at issue in this claim.

6. Under the Settlement Agreement, an eligible claimant or representative claimant is entitled to Level II benefits for damage to the mitral valve if the Diet Drug Recipient is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). The Trust does not contest that Mr. Harold had an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, and a reduced ejection fraction, each of which is one of the complicating factors necessary for a Level II claim.

where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrium Area ("LAA"). See Settlement Agreement § I.22.

In September, 2003, the Trust forwarded the claim for review by Maged M. Rizk, M.D., Ph.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Rizk concluded that there was no reasonable medical basis for the attesting physician's finding of severe mitral regurgitation based on Mr. Harold's August 12, 1998 echocardiogram because Mr. Harold only had mild mitral regurgitation. Specifically, Dr. Rizk explained, "[Mitral regurgitation] is not traced but appears only mild. More importantly this mild-moderate [mitral regurgitation] is diagnosed on [echocardiogram] on file in 9/1996 three months prior to earliest drug use and is associated by the severe cardiomyopathy which is also precedent to drug use."

Based on Dr. Rizk's finding that Mr. Harold had mild mitral regurgitation, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Mr. Harold contested this adverse determination.[7] In contest, claimant submitted affidavits from Dr. Evans, G. Whitney Reader, M.D., F.A.C.P.,

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

F.A.C.C., Gregory R. Boxberger, M.D., F.A.C.C., and Dan A. Francisco, M.D., F.A.C.C. Each of these physicians opined that claimant's August 12, 1998 echocardiogram was of adequate technical quality and concluded that it was reasonable for the attesting physician to state that Mr. Harold had at least moderate mitral regurgitation because the regurgitation shown was not an artifact, phantom jet, or backflow. Mr. Harold argued, therefore, that there was a reasonable medical basis for his claim because these Board Certified Cardiologists independently agreed that he had at least moderate mitral regurgitation. Mr. Harold further asserted that the auditing cardiologist "apparently did not understand the difference between his **personal opinion** ... and the 'reasonable medical basis' standard."

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Rizk submitted a declaration wherein he amended his Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue as follows: "I find a reasonable medical basis for the answer given by the Attesting Cardiologist to Green Form Question II.C.3.A that the Claimant does have moderate mitral regurgitation."

Based on Dr. Rizk's amended findings, the Trust issued a post-audit determination awarding Mr. Harold Matrix Benefits. Before the Trust paid Mr. Harold's claim, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. See PTO No. 3511

(May 10, 2004). Prior to entry of the stay, the Trust identified a number of Matrix claims that had passed audit but which the Trust alleged contained intentional material misrepresentations of fact. Following the end of the stay, we ordered the Trust to review these claims and issue new post-audit determinations, which claimants could contest. See PTO No. 5625 (Aug. 24, 2005).

On November 22, 2006, prior to the Trust's issuance of a new post-audit determination on Mr. Harold's claim, this court approved Court Approved Procedure ("CAP") No. 13, which provided these claimants with the option either to submit their claims to a binding medical review by a participating physician or to opt out of CAP No. 13. See PTO No. 6707 (Nov. 22, 2006). The Estate elected to opt out of CAP No. 13.[8]

The Trust therefore undertook to determine whether there were any intentional material misrepresentations of fact made in connection with the Estate's claim. As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the performance of echocardiographic studies and the resulting interpretations submitted in support of the Estate's claim. As stated in his March 22, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

> Mr. Harold has cardiomyopathy with mild mitral regurgitation. In Mr. Harold's study,

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8. Mr. Harold died on March 22, 2006, and the Estate was substituted as the proper party. Esther Harold was appointed Administratrix of Mr. Harold's Estate.

> the use of high color gain, high image gain and low frame rate and the selection of a still frame of backflow are the result of choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these factors exaggerated the appearance of regurgitation and jet duration. There is no responsible physiologic or hemodynamic construct under which this echocardiogram can be assessed as demonstrating severe or moderate mitral regurgitation. Mr. Harold has only mild mitral regurgitation-not severe mitral regurgitation as claimed by the Attesting Physician, Dr. Evans.[9]

Thus, notwithstanding Dr. Rizk's findings at audit, the Trust rescinded its prior final post-audit determination letter and issued a new post-audit determination denying the Estate's claim based on its conclusion that there was substantial evidence of intentional material misrepresentations of fact in connection with the claim. Pursuant to the Audit Rules, the Estate contested this adverse determination. In contest, the Estate made reference to the affidavits of Dr. Evans, Dr. Reader, Dr. Boxberger, and Dr. Francisco, none of whom the Estate says "noted any problem with either the color gain or frame settings."

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9. In November, 2004, the Trust had provided Mr. Harold with an "Expert Report" signed by Dr. Kisslo pursuant to Paragraph 11 of PTO No. 3883. In that report, Dr. Kisslo opined that Mr. Harold's echocardiogram "evidences a misrepresentation of the severity of mitral regurgitation." Dr. Kisslo explained, "Mr. Harold's echocardiogram demonstrates an excessively low color frame rate, which distorts the appearance of regurgitation. ... The two-dimensional echocardiogram demonstrated excessive gain, which results in destruction of spatial resolution and introduces random and system-induced noise into the image.... Mr. Harold's level of mitral regurgitation is mild."

The Estate also referenced the declaration of Dr. Rizk, who the Estate says "made no finding or mention of there being any problem with the color gain or frame rate setting."

In addition, the Estate submitted affidavits from Dr. Roeder; K.C. O'Neil-Vantuyl, the sonographer who performed Mr. Harold's echocardiogram; Ms. Harold; and the Estate's counsel. In his supplemental affidavit, Dr. Roeder stated, in pertinent part, that:

> 7. I have again reviewed Mr. Harold's echocardiogram of 08/12/98 and I stand by my previous interpretation, i.e., that it shows at least moderate mitral valve insufficiency, an ejection fraction of approximately 25% and left atrial enlargement measured at 5.8 cm. Dr. Kisslo's interpretation of this study is simply not accurate.
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> 8. The sonographer who performed this echocardiogram [K.C. O'Neil-Vantuyl], in her professional judgment, increased the color gain because of the patient's body habitus in order to get better tissue penetration, i.e., a better picture. The sonographer did not lower the frame rate, the machine did it automatically when the sonographer increased the depth because of Mr. Harold's body size, and widened the color box to go from a 2 chamber view of the heart to a 4 chamber view.
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> 9. The numerical color gain and frame rate setting for this echocardiogram were readily visible to Trust auditor Dr. Maged M. Rizk when he reviewed this tape while performing his audit. Dr. Rizk apparently had no quarrel with the echocardiogram color gain and/or frame rate settings since he found a "reasonable medical basis" for the finding of moderate mitral valve regurgitation and made no mention in his

Declaration of any irregularity in either the color gain or frame rate.

In her affidavit, Ms. O'Neil-Vantuyl stated, in pertinent part, that:

4. This echocardiogram was performed by me in the ordinary course of my practice, and was performed for the purpose of a medical diagnosis and treatment, and not for litigation. No lawyer or law firm requested that this echocardiogram be performed or interpreted, or paid for the echocardiogram or interpretation.

5. I would have had no interest [financial or otherwise] in intentionally manipulating or misrepresenting the findings of this echocardiogram.

6. Neither I or anyone else manipulated the echocardiogram machine control settings to distort, misrepresent or exaggerate the appearance of valvular regurgitation in this echocardiogram. The echocardiogram machine control settings during this echocardiogram were in conformity with my standard practice and protocol, and the standard practice and protocol of Cotton O'Neill Heart Center, for a transthoracic ehcocardiogram performed on a patient with this body habitus. This patient's weight was approximately 225 lbs. Using transducers available in 1998, the color gain was set higher. Color doppler analysis of mitral valve insufficiency was obtained in real time and still frame. The higher gain was used for better tissue penetration.

7. The echocardiogram settings for the echocardiogram performed on Thomas L. Harold on 08/12/98 were not intentionally manipulated to distort,

> exaggerate or misrepresent the amount of valvular regurgitation shown.[10]

In their respective affidavits, Ms. Harold and the Estate's counsel each confirmed that Mr. Harold's echocardiogram was performed in the ordinary course of regular medical treatment and not at the request of any lawyer.

Finally, the Estate argued that Dr. Kisslo's review of Mr. Harold's echocardiogram constitutes an impermissible second audit. According to the Estate, because the alleged intentional material misrepresentations of fact were obvious and not hidden, the Trust must pay the claim "even if there was an 'intentional manipulation.'"

The Trust then issued a new final post-audit determination, again denying the Estate's claim. In support, the Trust attached a supplemental declaration of Dr. Kisslo, wherein he concluded that there was "no proper purpose" for the settings on Mr. Harold's August 12, 1998 echocardiogram. Dr. Kisslo explained, among other things, that appropriate settings during Mr. Harold's September 13, 1996 echocardiogram and at the beginning of Mr. Harold's August 12, 1998 echocardiogram each produced studies of sufficient diagnostic quality. He concluded, therefore, that "[e]ach of these settings manipulations served only to distort the images of cardiac flow and, if unnoticed, distort the diagnostic process."

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10. Dr. Roeder offered similar testimony in his initial affidavit.

The Estate disputed the Trust's final determination and requested that the claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On September 26, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7439 (Sept. 26, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response on the Special Master, incorporating its prior submissions and raising the same arguments made in contest. On April 17, 2008, the Trust informed the Special Master that it intended to rely upon the documents previously submitted and the arguments that it had already raised. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[11] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to assign a Technical Advisor to aid it in resolving technical issues. Id.

review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden of proving that there is a reasonable medical basis for its claim. Where the Trust's post-audit determination finds intentional material misrepresentations of fact, the representative claimant has the burden of proving that all representations of material fact in connection with its claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer with no intentional material misrepresentations of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

> [T]he study was not conducted in a manner consistent with medical standards. There was no color flow evaluation of the mitral regurgitant jet in the apical two chamber view. The apical four chamber view was the only view that was appropriate for evaluation of the mitral regurgitant jet. Initially, the Nyquist limit was appropriately set at 69 cm per second at a depth of 23 cm and a color gain of 65%. There was no suggestion of excessive color gain at this setting. However, after a few cardiac cycles, the Nyquist limit was reduced to 59 cm per second at a depth of 23 cm and the color gain was increased to 91% of maximum. At this setting, there was excessive color gain and tremendous color artifact. Excessive color artifact was seen within the myocardial tissue. It was not possible to accurately assess the RJA at these settings. However, the RJA could be accurately assessed at the appropriate color Doppler settings of a Nyquist limit of 69 cm per second and the color gain of 65% of maximum. It should be noted that there was increased image gain and sparkling of tissues noted throughout the study. Overall, this was a below average echocardiographic study.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate Mr. Harold's echocardiogram and determined that there was no reasonable medical basis for finding that Mr. Harold had at least moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part, that:

> Visually, mild mitral regurgitation was suggested in the apical four chamber view at the proper color Doppler settings. There was no demonstration of color flow in the apical two chamber view. I digitized the cardiac cycles in the apical four chamber view and measured the LAA and RJA. The LAA in the apical four chamber view was 24.2 cm2. The largest representative RJA in the apical four chamber view at the appropriate Nyquist and color gain settings was 4.2 cm2. Therefore,

> the largest representative RJA/LAA ratio was 17%. There was no RJA/LAA ratio that reached 20% in this view with appropriate settings. Therefore, this study demonstrated mild mitral regurgitation. The RJA could not be accurately planimetered in those cardiac cycles in which the Nyquist limit was set lower at 59 cm per second and the color gain was increased to 91% of maximum. There was too much color artifact with color sparkling seen in the myocardium and even outside of the heart. There was one freeze frame of the supposed mitral regurgitant jet on this study in the apical four chamber view. This was not representative of mitral regurgitation and contained a great deal of artifact. This freeze frame occurred when there was a reduced Nyquist of 59 cm/sec and increased color gain setting of 91%.

In response to the Technical Advisor Report, the Estate argues that Dr. Vigilante was asked whether the echocardiogram of attestation was conducted in a manner consistent with medical standards rather than the appropriate questions: whether there was deliberate manipulation of Mr. Harold's echocardiogram, whether the conduct he identified would have been apparent to the Trust's auditor, and whether any alleged intentional manipulation amounted to a material misrepresentation of fact in connection with the claim. Finally, the Estate repeats its argument that Dr. Kisslo's review constitutes an unauthorized re-audit.[12]

After reviewing the entire show cause record, we find the Estate has not established a reasonable medical basis for

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12. The Estate also requested, and the Special Master denied, leave to present additional evidence with its response to the Technical Advisor Report. We previously have explained that such additional evidence is not permitted by Audit Rule 34. See, e.g., Mem. in Supp. of PTO No. 9041, at 9-10 n.11 (Apr 5, 2013).

finding that Mr. Harold had at least moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of these two documents, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Kisslo and Dr. Vigilante found that claimant's sonographer improperly selected, traced, and measured a supposed regurgitant "jet." According to Dr. Kisslo, the still frame included backflow, rather than mitral regurgitant flow. Dr. Vigilante similarly concluded that the sonographer's measurement on this "freeze frame of the supposed mitral regurgitant jet ... was not representative of mitral regurgitation and contained a great deal of artifact." In addition, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner

consistent with medical standards because, among other things, the echocardiogram settings included excessive color gain, a high image gain, and an improperly decreased Nyquist setting.

Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that Mr. Harold's echocardiogram demonstrated only mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the conclusions of the Estate's experts that Mr. Harold had at least moderate mitral regurgitation. Specifically, he explained that "the largest representative RJA/LAA ratio was 17%" and that "this study demonstrated mild mitral regurgitation."

The Estate's only substantive challenge to the specific findings of Dr. Kisslo and Dr. Vigilante regarding the manner in which Mr. Harold's echocardiogram was conducted relates to the opinion of Dr. Roeder and Ms. O'Neil-Vantuyl that the echocardiogram settings were the result of the machine used and Mr. Harold's body structure. Dr. Kisslo, however, reviewed Mr. Harold's September 13, 1996 and August 12, 1998 echocardiogram and determined there was "no proper purpose for the changed settings between 1996 and 1998." In addition, he stated that "the 1998 echocardiogram tape demonstrates that the appropriate settings used in the early part of the study were not only possible, but they actually produced a study of sufficient diagnostic value that there was no need to adjust the settings later in the study." Dr. Vigilante also observed:

> Initially, the Nyquist limit was appropriately set at 69 cm per second at a depth of 23 cm and a color gain of 65%. There was no suggestion of excessive color gain at this setting. However, after a few cardiac cycles, the Nyquist limit was reduced to 59 cm per second at a depth of 23 cm and the color gain was increased to 91% of maximum. At this setting, there was excessive color gain and tremendous color artifact. Excessive color artifact was seen within the myocardial tissue.

The Estate did not attempt to rebut the specific findings of Dr. Kisslo or Dr. Vigilante in this regard.

We also reject the Estate's argument that the review of its claim by Dr. Kisslo constitutes an impermissible second audit. This argument ignores the plain language of the Audit Rules, which provides that the Trust must conduct a review separate from the auditing cardiologist with respect to whether there were any intentional material misrepresentations of fact in connection with a claim. Specifically, the Audit Rules state, in pertinent part, that:

> The Auditing Cardiologist shall review a Claim in accordance with these Rules to determine whether there was a reasonable medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue ("GREEN Form Question at Issue"). The Trust shall review a Claim to determine whether there were any intentional material misrepresentations made in connection with the Claim. The Trust may consider information from other Claims in Audit to determine the existence of facts or a pattern of misrepresentations implicating intentional misconduct by an attorney and/or physician that may warrant relief pursuant to Section VI.E.8 of the Settlement Agreement.

Audit Rule 5. Based on the findings of Dr. Kisslo, the Trust denied the Estate's claim, determining that the claim was based on one or more intentional material misrepresentations of fact.

The Estate disputed this determination and proceeded to the show cause process. We need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with the Estate's claim given our conclusion, based on our review of the entire record, that there is no reasonable medical basis for finding that Mr. Harold had at least moderate mitral regurgitation.[13]

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there is a reasonable medical basis for finding that Mr. Harold had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix Benefits and the related derivative claim submitted by Mr. Harold's spouse.

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13. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625, at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.